UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/523,243	10/12/2005	Michael Brock	Muller-47	6495

39703 7590 01/05/2009

C. JAMES BUSHMAN
5851 San Felipe
SUITE 975
HOUSTON, TX 77057

EXAMINER	
SOROUSH, LAYLA	
ART UNIT	PAPER NUMBER
1617	

MAIL DATE	DELIVERY MODE
01/05/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/523,243	BROCK ET AL.	
	Examiner	Art Unit	
	LAYLA SOROUSH	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 September 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11 and 18-27* is/are pending in the application.

4a) Of the above claim(s) *18-24 and 27* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11 and 25-26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The Office Action is in response to the Applicant's reply filed September 24, 2008 to the Office action mailed on March 24, 2008.

Applicant's arguments over the 35 U.S.C. 112, second paragraph, of claim 7 is not persuasive but in view of cancellation of the claims the rejection of record is herewith withdrawn.

Applicant's arguments over the 35 U.S.C. 112, second paragraph, of claim 12 is not persuasive but in view of cancellation of the claims the rejection of record is herewith withdrawn.

Applicant's arguments over the 35 U.S.C. 101 of claim 12 is not persuasive but in view of cancellation of the claims the rejection of record is herewith withdrawn.

Applicant's arguments over the 35 U.S.C. 103 (a) rejection of claims 1-12 and 25-26 over Brock et al. ((IDS) WO 00/47166 – English equivalent US Applic. No. 09/890696) in view of Hasegawa (JP 06234628A), Domsch et al. (DE 10058328A1) and Ansmann et al. (US 6365168 B1) is not persuasive. Therefore, the rejection of record is herewith maintained.

Claim 27 is withdrawn from further consideration pursuant to 37 C.F.R. 1.142(b), as being drawn to non-elected subject matter.

The following rejections are reiterated for Applicants convenience:

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-11 and 25-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brock et al. ((IDS) WO 00/47166 – English equivalent US Applic. No. 09/890696) in view of Hasegawa (JP 06234628A), Domsch et al. (DE 10058328A1) and Ansmann et al. (US 6365168 B1).

Brock et al. teaches a medicinal-dermatologic microemulsion comprising (A) 0.5 to 70 % by weight of alkanolammonium salts of the alkylsulfates and/or alkylpoly-alkyleneglycolethersulfates having the following structure R^1-O-$(C_pH_{2p}O)_m$-SO_3-$HN^+R^2R^3R^4$, where R^1 = is a C_8- to C_{20}-hydrocarbon residue, p = is an integer from 2 to 5, where p can be different for each m, R^2 = H, a C_1- to C_6-alkyl, or a C_2- to C_4- hydroxyalkyl, R^3 = H, a C_1- to C6-alkyl, or a C_2- to C_4-hydroxyalkyl, R^4 = a C_2- to C_4-hydroxyalkyl, preferably a C3-hydroxypropyl, and m = is an integer from 0 to 7, (B) 20 to 95 % by weight of water, (C) 0.1 to 20 % by weight of one or more oil component(s), and (D) 0.1 to 20 % by weight, preferably 0.1 to 15 % by weight of one or more mono- or polyhydric, preferably mono-, di-, or trihydric C_2- to C_4- alcohol(s), preferably C_2- to C_6-alcohol(s) (p.5 and 6), as recited in claims 1 in part and 12. Further, Brock et al. teaches “The compositions according to the present invention most preferably contain alkanolammonium salts of the alkyl- sulfates and/or

alkylpolyalkyleneglycolethersulfates of the aforesaid general structure. Preferably, they have independently of one another the following radicals: R1 = C12- to C16-alkyl, the alkyl residue being linear and saturated, p = 2 or 3, where p can be different for each m, R^2= H or hydroxyisopropyl, R^3 = H or hydroxyisopropyl, R4 = hydroxyisopropyl, and m = 0, 1, or 2 (p 8 lines 10-16)," as recited in claim 5 The microemulsions contain : (A) 2 to 60 % by weight, preferably 20 to 40 % by weight, (B) 30 to 80 % by weight, preferably 40 to 60 % by weight, (C) 0.5 to 15 % by weight, preferably 4 to 10 % by weight, (D) 0.1 to 9 % by weight, preferably 0.5 to 9 % by weight, (E) 0 to 20 % by weight, preferably 3 to 15 % by weight of additional surfactants, (F) 0 to 20 % by weight, preferably 1 to 12 % by weight of electrolytes, and (G) 0 to 10 % by weight, preferably 0.1 to 8 % by weight of additives (p. 6 and 7), as recited in claims 6 and 7. Brock et al. teaches "as an additional surfactant is a triglyceride alkoxylated with ethyleneoxide and/or propylene- oxide and subsequently esterified, wholly or in part, with C6- to C22-fatty acids (p. 7)," as recited in claim 8. The oil components of the present invention are advanta\- geously chosen from the group of lecithins and the group of mono-, di-, and/or triglycerides of saturated and/or unsaturated, branched and/or linear alkylcarboxylic acids having chain lengths of from 8 to 24, particularly from 12 to 18 carbon atoms. The fatty acid triglycerides can advantageously be synthetic, semisynthetic, or natural oils, such as soya oil, castor oil, olive oil, safflower oil, wheatgerm oil, grapeseed oil, sunflower oil, peanut oil, almond oil, palm oil, coconut oil, thistle oil, evening primrose oil, rape oil, etc. The oil component can furthermore comprise vaseline, paraffin oil, and

polyolefins. Moreover, the oil components according to the present invention can advantageously be selected from the group of esters of saturated and/or unsaturated, branched and/or linear alkylcarboxylic acids having chain lengths of from 3 to 30 carbon atoms and of saturated and/or unsaturated, branched and/or linear alcohols having chain lengths of from 3 to 30 carbon atoms. It is furthermore advantageous to select the oil components from the group of esters of aromatic carboxylic acids and saturated and/or unsaturated, branched and/or linear alcohols having chain lengths of from 3 to 30 carbon atoms, which ester oils can advantageously be chosen from the group of isopropyl myristate, isopropyl palmitate, isopropyl stearate, isopropyl oleate, n-butyl stearate, n-hexyl laurate, n-decyl oleate, isooctylstearate, isononylstearate, isononylisononanoate, 2-ethylhexylpalmitate, 2-ethylhexyllaurate, 2-hexyldecyl- stearate, 2-octyldodecylpalmitate, oleyl oleate, oleyl erucate, erucyl oleate, erucyl erucate, and synthetic, semisynthetic, and natural mixtures of such esters, e.g. jojoba oil. Furthermore, the oil component can advantageously be selected from the group of branched and linear hydro\- carbons and hydrocarbon waxes and silicone oils. Any mixtures of the aforesaid oil components are also advantageous within the meaning of the present invention (p. 8 and 9)," as recited in claim 9. The microemulsion is stable, optically transparent and the average particle size is preferably less than 100 nm (p. 7), as recited in claim 10. The reference teaches "preferably, the microemulsions of the invention contain no or at most only small quantities (less than 1.5 % by weight) of polyhydroxyfatty acid amides (so-called glucamides). Moreover, it is preferable that the composition of the invention

contains no or at most only small amounts (less than 0.5 % by weight) of anionic surfactants of the sulfonate type (p. 11)," as recited in claim 11. The additives used by Brock et al. include vitamins and preservatives.

The reference fails to specifically teach the additive UV filters such as octocrylenes, 4-methoxycinnamic acid-2-ethylhexyl ester, 2-phenylbenzimidazol-5-sulfonic acid, 2-hydroxy-4-methoxybenzophenone sulfonic acid, and 4-bis(polyethoxy)paraminobenzoic acid polyethoxyethyl ester, and mixtures thereof and anti-dandruff agents.

Hasegawa is solely used to show that nicotinic acid (3-aminopyridine niacinamide-vitamin) and its derivatives are useful in treating dandruff (or are anti-dandruff agents) (Abstract).

Domsch et al. is solely used to show that climbazol (1-(4-chlorophenoxy-1-(1-H-imidazol-1-yl)-3,3,-di-methyl-2-butanone) is a preservative and an antidandruff agent (Abstract).

Ansmann et al. is solely used to show that climbazol is an antidandruff agent and that "secondary light filters of the antioxidant type, which interrupt the photochemical reaction chain initiated when UV radiation penetrates into the skin" are useful in topical cosmetics. "Typical examples of these secondary light filters are Superoxid-Dismutase, Tocopherols (vitamin E) and ascorbic acid (vitamin C)."

Ansmann et al. further teaches UV filters are organic compounds which are capable of absorbing ultraviolet rays and of releasing the energy absorbed in the form of longer wave radiation, for example heat. Typical examples are 4-

aminobenzoic acid and esters and derivatives thereof (for example 2-ethylhexyl-p-dimethylaminobenzoate or p-dimethylaminobenzoic acid octyl ester), methoxycinnamic acid and derivatives thereof (for example 4-methoxycinnamic acid-2-ethylhexyl ester), benzophenones (for example oxybenzone, 2-hydroxy-4-methoxybenzophenone), dibenzoyl methanes, salicylate esters, 2-phenyl benzimidazole-5-sulfonic acid, 1-(4-tert.butylphenyl)-3-(4'-methoxyphenyl)-propane-1,3-dione, 3-(4'-methyl)-benzylidenebornan-2-one, methyl-benzylidene camphor and the like. Other suitable UV filters are finely disperse metal oxides and salts, for example titanium dioxide, zinc oxide, iron oxide, aluminium oxide, cerium oxide, zirconium oxide, silicates (talcum) and barium sulfate.

It would have been obvious to one of ordinary skill in the art to incorporate the UV filters and antidandruff substances into the composition of Brock et al. The motivation to make such an incorporation is because Brock et al. teaches the use of additives such as preservatives, antioxidants, and vitamins (which are also UV filters and antidandruff agents as taught by Hasegawa, Domsch et al., and Ansmann et al. references) in the microemulsion. Hence a skilled artisan would have reasonable expectation of successfully producing a stable medicinal-dermatologic microemulsion by incorporating the UV filter and antidandruff agents.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where

the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1,5-11 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 11-17 and 20 of copending Application No. 09890696. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the copending application are drawn to microemulsion comprising (A) 0.5 to 70 % by weight of alkanolammonium salts of the alkylsulfates and/or alkylpoly-alkyleneglycolethersulfates having the following structure R^1-O- $(C_pH_{2p}O)_m$-SO_3-$HN^+R^2R^3R^4$, where R^1 = is a C_8- to C_{20}-hydrocarbon residue, p = is an integer from 2 to 5, where p can be different for each m, R^2 = H, a C_1- to C_6-alkyl, or a C_2- to C_4- hydroxyalkyl, R^3 = H, a C_1- to C6-alkyl, or a C_2- to C_4- hydroxyalkyl, R^4 = a C_2- to C_4-hydroxyalkyl, preferably a C3-hydroxypropyl, and m = is an integer from 0 to 7, (B) 20 to 95 % by weight of water, (C) 0.1 to 20 % by weight of one or more oil component(s), and (D) 0.1 to 20 % by weight, preferably 0.1 to 15 % by weight of one or more mono- or polyhydric, preferably mono-, di-, or trihydric

C_2- to C_4- alcohol(s), preferably C_2- to C_6-alcohol(s) (p.5 and 6), as recited in claims 1 in part and 12. Further, Brock et al. teaches "The compositions according to the present invention most preferably contain alkanolammonium salts of the alkyl- sulfates and/or alkylpolyalkyleneglycolethersulfates of the aforesaid general structure. Preferably, they have independently of one another the following radicals: R1 = C12- to C16-alkyl, the alkyl residue being linear and saturated, p = 2 or 3, where p can be different for each m, R^2= H or hydroxyisopropyl, R^3 = H or hydroxyisopropyl, R4 = hydroxyisopropyl, and m = 0, 1, or 2 (p 8 lines 10-16)," as recited in claim 5 The microemulsions contain : (A) 2 to 60 % by weight, preferably 20 to 40 % by weight, (B) 30 to 80 % by weight, preferably 40 to 60 % by weight, (C) 0.5 to 15 % by weight, preferably 4 to 10 % by weight, (D) 0.1 to 9 % by weight, preferably 0.5 to 9 % by weight, (E) 0 to 20 % by weight, preferably 3 to 15 % by weight of additional surfactants, (F) 0 to 20 % by weight, preferably 1 to 12 % by weight of electrolytes, and (G) 0 to 10 % by weight, preferably 0.1 to 8 % by weight of additives whereas the instant claims are drawn to a micoremulsion comprising (A) 0.5 to 70 % by weight of alkanolammonium salts of the alkylsulfates and/or alkylpoly-alkyleneglycolethersulfates having the following structure R^1-O- $(C_pH_{2p}O)_m$-SO_3-$HN^+R^2R^3R^4$, where R^1 = is a C_8- to C_{20}-hydrocarbon residue, p = is an integer from 2 to 5, where p can be different for each m, R^2 = H, a C_1- to C_6-alkyl, or a C_2- to C_4- hydroxyalkyl, R^3 = H, a C_1- to C6-alkyl, or a C_2- to C_4- hydroxyalkyl, R^4 = a C_2- to C_4-hydroxyalkyl, preferably a C3-hydroxypropyl, and m = is an integer from 0 to 7, (B) 20 to 95 % by weight of water, (C) 0.1 to 20 % by weight of one

or more oil component(s), and (D) 0.1 to 20 % by weight, preferably 0.1 to 15 % by weight of one or more mono- or polyhydric, preferably mono-, di-, or trihydric C_2- to C_4- alcohol(s), preferably C_2- to C_6-alcohol(s) and additional ingredients of UV filters and anti-dandruff substances.

It would have been obvious to one of ordinary skill in the art at the time of the invention to incorporate the UV filter and antidandruff agents to the medicinal-dermatologic microemulsion with reasonable expectation of successfully producing a stable medicinal-dermatologic composition.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Arguments

Applicants' arguments and Declaration are that the composition of the claimed invention and conventional shampoos obtain similar results although the amounts of the antidandruff agent of the claimed invention is 2/3 or even 1/3 of that in the conventional shampoo preparation. Examiner states that Applicant's 132 Declaration has been considered but is not persuasive. The Declaration does not commensurate in scope with the claimed invention. The claims are drawn to a composition comparison 0.1 to 3% by weight of one or more antidandruff substance(s) and mixtures thereof. The references relied upon, more specifically, Domsch et al. teaches 0.1 to 3% climbazol in the composition (see abstract).

Also, Applicant argues the "As can be seen from the data in the table on page 3 of Exhibit F, Duschgel 2, using the Claimed Microemulsion and the

sunscreen agent, Parsol MCX, exhibits UV filtering capacity twice as high as the straight microemulsion without any sunscreen additive." Examiners contention is that the statement above is not considered unexpected.

Lastly, Applicant argues shower gels are rinse off but the Exhibits show significant residual protection against UV radiation remains on the skin. Examiner points to the Ansmann et al. reference which is also a shampoo (rinse off) comprising UV filters. Ansmann et al. teaches light filters interrupt the photochemical reaction chain initiated when UV radiation penetrates into the skin.

Applicants arguments have been considered but are not persuasive.

Applicant is asked to provide a clear copy of EXHIBITS A-F. The labels of the documents provided read 1-7 and Applicant discusses EXHIBITS A-F.

The arguments are not persuasive and the rejection is made **FINAL**.

Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will

the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Conclusion

No claims allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Layla Soroush whose telephone number is (571)272-5008. The examiner can normally be reached on Monday through Friday from 8:30 a.m. to 5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/SREENI PADMANABHAN/
Supervisory Patent Examiner, Art Unit 1617